

Department of Health and Human Services

§ 170.520

§ 170.503 Requests for ONC-AA status and ONC-AA ongoing responsibilities.

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(b) * * *

(1) A detailed description of the accreditation organization's conformance to ISO/IEC17011 (incorporated by reference in §170.599) and experience evaluating the conformance of certification bodies to ISO/IEC 17065 (incorporated by reference in §170.599).

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(e) * * *

(1) Maintain conformance with ISO/IEC 17011 (incorporated by reference in §170.599);

(2) Verify that the certification bodies it accredits and ONC-ACBs conform to, at a minimum:

(i) For fiscal years 2014 and 2015, ISO/IEC Guide 65 (incorporated by reference in §170.599); and

(ii) For fiscal year 2016 and subsequent years, ISO/IEC 17065 (incorporated by reference in §170.599).

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§ 170.504 Reconsideration process for requests for ONC-AA status.

(a) An accreditation organization that submits a timely request for ONC-AA status in accordance with §170.503 and is denied may request reconsideration of the decision to deny its request for ONC-AA status.

(b) *Submission requirement.* To request reconsideration, an accreditation organization is required to submit to the National Coordinator, within 15 days of receipt of a denial notice, a written statement with supporting documentation contesting the decision to deny its request for ONC-AA status. The submission must demonstrate that clear, factual errors were made in the review of its request for ONC-AA status and that the accreditation organization would have been selected as the ONC-AA pursuant to §170.503(c) if those errors had been corrected. If the National Coordinator does not receive an accreditation organization's submission within the specified timeframe, then its request for reconsideration may be denied.

(c) *Review of submissions.* The National Coordinator is permitted up to 30 days to review all timely submissions that were received and determine

whether an accreditation organization has met the standard specified in paragraph (b) of this section.

(d) *Decision.* (1) If the National Coordinator determines that an accreditation organization has met the standard specified in paragraph (b) of this section, then that organization will be approved as the ONC-AA on a final basis. All other accreditation organizations will be notified that their requests for reconsideration have been denied.

(2) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

§ 170.505 Correspondence.

(a) Correspondence and communication with the National Coordinator shall be conducted by e-mail, unless otherwise necessary. The official date of receipt of any e-mail between the National Coordinator and an accreditation organization requesting ONC-AA status, the ONC-AA, an applicant for ONC-ACB status, or an ONC-ACB is the date on which the e-mail was sent.

(b) In circumstances where it is necessary for an accreditation organization requesting ONC-AA status, the ONC-AA, an applicant for ONC-ACB status, or an ONC-ACB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt will be the date of the delivery confirmation.

§ 170.510 Types of certification.

Applicants may seek authorization from the National Coordinator to perform the following types of certification:

(a) Complete EHR certification; and/or

(b) EHR Module certification; and/or

(c) Certification of other types of HIT for which the Secretary has adopted certification criteria under subpart C of this part.

§ 170.520 Application.

Applicants must include the following information in an application for ONC-ACB status and submit it to the National Coordinator for the application to be considered complete.

(a) The type of authorization sought pursuant to §170.510. For authorization